Patent Claims

1. Complexes of nucleic acid and polyethyleneimine (PEI), characterised in that the PEI is modified with a hydrophilic polymer covalently coupled thereto.

2. Complexes according to claim 1, characterised in that the nucleic acid is DNA and the ratio of DNA to PEI, expressed by the molar ratio of the nitrogen atoms in the PEI to the phosphate atoms in the DNA (N/P value), is about 0.5 to about 100.

3. Complexes according to claim 2, characterised in that the N/P value is about 2 to about 20.

4. Complexes according to claim 3, characterised in that the N/P value is about 3 to about 10.

5. Complexes according to one of the preceding claims, characterised in that the PEI has a molecular weight of about 700 D to about 2,000,000 D.

6. Complexes according to claim 5, characterised in that the PEI has a molecular weight of about 2,000 D to about 800,000 D.

7. Complexes according to one of the preceding claims, characterised in that the hydrophilic polymer is linear.

8. Complexes according to one of the preceding claims, characterised in that the hydrophilic polymer is selected from among the group of polyethyleneglycols (PEG), polyvinylpyrollidones, polyacrylamides, polyvinylalcohols, or copolymers thereof.

9. Complexes according to claim 8, characterised in that the hydrophilic polymer is PEG.

10. Complexes according to claim 8 or 9, characterised in that the molecular weight of the hydrophilic polymer is about 500 D to about 20,000 D.

11. Complexes according to claim 10, characterised in that the molecular weight of the hydrophilic polymer is about 1,000 D to about 10,000 D.

12. Complexes according to one of the preceding claims, characterised in that the molar ratio of polymer: primary amino groups/PEI is about 1:10 to about 10:1.

13. Complexes according to claim 12, characterised in that the ratio is about 1:5 to about 5:1.

14. Complexes according to claim 13, characterised in that the ratio is about 1:3 to about 1:1.

15. Complexes according to one of the preceding claims, characterised in that PEI is modified with a cellular ligand.

16. Complexes according to claim 15, characterised in that the ligand is transferrin.

17. Complexes according to claim 15, characterised in that the ligand is EGF.

18. Complexes according to claim 15, characterised in that PEI is bound to the ligand via the hydrophilic polymer.

19. Complexes according to one of the preceding claims, characterised in that they contain, as the nucleic acid, a therapeutically active nucleic acid.

20. Complexes according to claim 19, characterised in that the therapeutically active nucleic acid codes for one or more cytokines.

21. Complexes according to claim 19, characterised in that the therapeutically active nucleic acid codes for one or more tumour antigens or fragments thereof.

22. Complexes according to claim 19, characterised in that the therapeutically active nucleic acid is a suicide gene.

23. Complexes according to claim 22, characterised in that the suicide gene is the Herpes Simplex thymidine kinase gene.

24. Process for preparing complexes according to one of claims 1 to 23, characterised in that first DNA and PEI, optionally modified with a cellular ligand, are complexed by mixing the dilute solutions and then the hydrophilic polymer is bound to PEI.

25. Process according to claim 24, characterised in that the DNA concentration is about 5 to 50 µg of DNA/ml.

26. Process according to claim 25, characterised in that the DNA concentration is about 10 to 40 µg of DNA/ml.

27. Process according to claim 25 or 26, characterised in that the complexing is carried out at a salt concentration below the physiological value.

28. Process according to claim 27, characterised in that the complexing is carried out in deionised water.

29. Preparation process according to one of claims 24 to 28, characterised in that after the complexing of

DNA and optionally modified PEI, the complexes of the dilute solution are adjusted to a concentration of about 200 µg/ml to 1 mg/ml, based on DNA.

30. Composition for the transfection of mammalian cells, characterised in that it contains one or more complexes according to one of claims 1 to 23 in a concentration of 200 µg/ml to 1 mg/ml, based on DNA.

31. Pharmaceutical composition containing one or more complexes according to claim 19.

32. Pharmaceutical composition according to claim 31, characterised in that it contains the complexes in a concentration of about 200 µg/ml to about 1 mg/ml, based on DNA.

33. Pharmaceutical composition according to claim 31 or 32, characterised in that the complexes contain DNA which codes for one or more cytokines.

34. Pharmaceutical composition according to claim 31 or 32 in the form of a tumour vaccine, characterised in that the complexes contain DNA which codes for one or more tumour antigens or fragments thereof, optionally combined with DNA which codes for one or more cytokines.

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